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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,417	WATANABE ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-19* is/are pending in the application.

4a) Of the above claim(s) *5,6,10-16 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7-9,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-3 and 5-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/830,428.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 12 July 2006 has been entered in full. Claims 1-2, 7-9, and 17-18 are amended. Claim 4 is cancelled.

Claims 5-6, 10-16, and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 31 January 2006.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 7-9, and 17-18 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

1. The objection to the drawings because of duplicative sequences in the Figures and sequence listing as set forth at pg 2-3 of the previous Office Action (12 April 2006) is *withdrawn* after reconsideration by the Examiner. The effective date of the rule change is 21 October 2004 and the application was filed on 05 February 2004 (See 37 CFR 1.58(a) and 37 CFR 1.83).

2. The objections to the abstract and specification as set forth at pg 3 of the previous Office Action (12 April 2006) are *withdrawn* in view of the amended abstract and specification (12 July 2006).

3. The objections of claims 1-2, 4, and 8-9 as set forth at pg 4 of the previous Office Action (12 April 2006) are *withdrawn* in view of the amended and cancelled claims (12 July 2006).

4. The rejections of claims 1 and 4 under 35 U.S.C. § 112, first paragraph (scope of enablement and written description) as set forth at pg 4-6 and 8-11 of the previous Office Action

(12 April 2006) are *withdrawn* in view of the amended and cancelled claims (12 July 2006). Please see section on 35 U.S.C. § 112, first paragraph, below.

5. The rejection of claims 1, 3-4, 7-9, and 17-18 under 35 U.S.C. § 112, second paragraph as set forth at pg 11 of the previous Office Action (12 April 2006) is *withdrawn* in view of the amended and cancelled claims (12 July 2006).

6. The rejection of claims 1-4, 8-9, and 17-18 under 35 U.S.C. § 102(e) as set forth at pg 12 of the previous Office Action (12 April 2006) is *withdrawn* in view of the amended and cancelled claims and submission of the certified translation of foreign priority document H11(1999)-027710 filed2/4/1999 (12 July 2006).

Claim Rejections - 35 USC § 102

7. Claim 2-3, 7, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bell et al. (U.S. Patent 5,436,155). It is noted that the Examiner has interpreted claim 2 as encompassing an infinite number of polynucleotides that hybridize to the nucleic acid sequence of SEQ ID NO: 6.

Bell et al. teach an isolated nucleic acid sequence that is 14.6% identical to the nucleic acid sequence of SEQ ID NO: 6 of the instant application (Please see SEQ ID NO: 9 of Bell et al. and the sequence alignment attached to the Office Action of 12 April 2006). Thus, Bell et al. teach an isolated nucleic acid that hybridizes to the nucleic acid sequence of SEQ ID NO: 6 of the instant application. Bell et al. also teach a composition comprising the somatostatin receptor DNA of SEQ ID NO: 9 (col 5, lines 42-63). Bell et al. disclose vectors and host cells comprising the DNA of SEQ ID NO: 9 (col 8, lines 12-68 through col 10).

Applicant's arguments (12 July 2006), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

At pg 14 of the Response, Applicant asserts that amended claim 1 now requires a nucleotide sequence, which hybridizes under high stringent conditions to the nucleotide sequence of SEQ ID NO: 6, wherein the high stringent conditions comprise a sodium concentration at about 19mM and a temperature at about 65° C. Applicant argues that these hybridization conditions exclude the nucleotide sequence in Bell. Applicant cites pg 6.58 of "Molecular Cloning: A Laboratory Manual" in support of this position. Applicant states that members of a gene family from a single species or orthologous genes from different species can almost always be isolated by low stringency hybridization if they share 65% or greater sequence identity.

Applicant's arguments have been fully considered but are not found to be persuasive. The state of the art is such that the washing conditions in a hybridization assay remove unbound or non-specifically bound sequences, washing away unwanted signal and background (Herzer and Englert. "Nucleic Acid Hybridization". (2001) Molecular Biology Problem Solver: A Laboratory Guide. New York:Wiley-Liss, page 434-345; Wallace et al., Methods Enzym 152: 432-442, 1987, especially pg 439-440; pg 6.58 of "Molecular Cloning: A Laboratory Manual", as cited by Applicant). However, regarding claim 2, since there is no recitation of washing conditions in the claim, an infinite number of polynucleotides may hybridize to the nucleotide sequence of SEQ ID NO: 6, including the nucleic acid molecule of Bell et al.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-3, 7-9, and 17-18 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation.

The claims are directed to an isolated polynucleotide comprising a nucleotide sequence selected from the group consisting of the nuceleotide sequence of SEQ ID NO: 6 and a nucleotide sequence which encodes the amino acid sequence of SEQ ID NO: 5. The claims recite an isolated polynucleotide comprising a nucleotide sequence which hybridizes under high stringent conditions to the nucleotide sequence of SEQ ID NO: 6. The claims recite an agent comprising the polynucleotide, a recombinant vector, and an isolated transformant comprising the vector.

The specification of the instant application teaches the isolation of cDNA encoding the novel G protein coupled receptor protein derived from the rat cerebellum and from the human brain (pg 5, lines 26-33; 108-110). The specification discloses that the receptor protein and the DNA encoding the receptor protein possess a cancer metastasis suppressing activity, as well as a placenta function regulating activity (pg 70, lines 18-34). However, the instant specification does not teach any physiological significance or functional characteristics of the claimed human OT7T175 polynucleotide (SEQ ID NO: 6) or polypeptide (SEQ ID NO: 6). The specification also does not disclose any methods or working examples that indicate the hOT7T175 polynucleotides and polypeptide of the instant invention are involved in any specific activity. It is not clear what biological activity or any other specific feature is associated with a "cancer suppressing activity" or "placenta function regulating activity". Without any information as to

the specific properties of hOT7T175, the mere identification of the polypeptide is not sufficient to impart any particular utility to the claimed polynucleotides. Since significant further research would be required of the skilled artisan to determine how the claimed polynucleotide and polypeptide are involved in any activities, the asserted utilities are not substantial. Since the utility is not presented in mature form and significant further research is required, the utility is not substantial. The specification asserts the following as patentable utilities for the claimed putative hOT7T175 nucleic acid (SEQ ID NO: 6):

1) to design antisense DNA (pg 31, lines 22-33 through pg 35, lines 1-19)

2) to treat diseases (pg 32, lines 4-5; pg 69-75; pg 90, line 33 through pg 91, line 7)

3) to diagnose diseases (pg 32, lines 4-5; pg 69-75; pg 90, line 33 through pg 91, line 7)

4) to search for ligands, agonists, and antagonists (pg 51-55; pg 75, lines 21-34 through pg 81)

5) to generate transgenic animals (pg 100, lines 29-34 through pg 102)

Each of these shall be addressed in turn.

1) to design antisense DNA. This asserted utility is not specific or substantial. Antisense oligonucleotides can be designed from any polynucleotide sequence. Further, the specification does not disclose a specific DNA target. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

2) to treat diseases. This asserted utility is not specific or substantial. Such can be performed for any nucleic acid. Further, the specification does not disclose diseases associated with an upregulated, downregulated, mutated, deleted, or translocated hOT7T175 (SEQ ID NO: 6). Significant further experimentation would be required of the skilled artisan to identify

individuals with such a disease. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

3) to diagnose diseases. This asserted utility is not specific or substantial. Such assays can be performed with any polynucleotide. Further, the specification does not disclose the tissues or cell types the polynucleotide is normally or abnormally expressed in. The specification also discloses nothing about the normal levels of expression of the polynucleotide or a specific DNA target. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

4) to search for ligands, agonists, and antagonists. This asserted utility is not specific or substantial. Such assays can be performed with any polynucleotide. Nothing is disclosed about how the polynucleotide is affected by the compounds. Additionally, the specification discloses nothing specific or substantial for the hOT7T175 ligands, agonists and antagonists screened in this method. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

5) to generate transgenic animals. This asserted utility is not specific or substantial. The specification does not disclose diseases associated with an upregulated, downregulated, mutated, deleted, or translocated hOT7T175 gene (SEQ ID NO: 6). The specification discloses nothing about whether the gene will be "knocked in" or "knocked out" or what specific tissues and cells are being targeted. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

It is clear from the instant specification that the hOT7T175 receptor polypeptide

described therein is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this DNA and protein, may be found to have a specific and substantial asserted utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

9. Claims 1-3, 7-9, and 17-18 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

10. However, even if the claimed invention is eventually deemed to have a credible, specific and substantial asserted utility or a well established utility, claims 2-3, 7-9, and 17-18 would remain rejected under 35 U.S.C. § 112, first paragraph. (Please note that the basis of this issue was set forth for claims at pg 5-8 of the previous Office Action (12 April 2006)).

Applicant's arguments (12 July 2006), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

(i) Applicant argues that claim 2 is direct to an isolated polynucleotide comprising a nucleotide sequence, which hybridizes under high stringent conditions to the nucleotide sequence of SEQ ID NO: 6, wherein the high stringent conditions comprise a sodium concentration at about 19mM and a temperature at about 65° C. Applicant states that hybridization techniques and procedures are common and well known in the biotech industry. Applicant submits that it is well established in the art that the term stringent conditions refers to hybridization and washing under conditions that permit only binding of nucleic acid molecule, such as an oligonucleotide or cDNA molecule, to highly homologous sequences. Applicant contends that the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation and cites MPEP § 2164.04. Applicant concludes that the hybridization techniques and procedures are common and well known in the biotech industry and it would require only routine experimentation for the skilled artisan to isolate DNA sequences that hybridize under the highly stringent conditions recited in the claims.

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, the state of the art is such that the washing conditions in a hybridization assay remove unbound or non-specifically bound sequences, washing away unwanted signal and

background (Herzer and Englert. "Nucleic Acid Hybridization". (2001) Molecular Biology Problem Solver: A Laboratory Guide. New York:Wiley-Liss, page 434-345; Wallace et al., Methods Enzym 152: 432-442, 1987, especially pg 439-440; pg 6.58 of "Molecular Cloning: A Laboratory Manual", as cited by Applicant). Thus, regarding claims 2-3, 7-9 and 17-18, since there is no recitation of washing conditions in the claims, an infinite number of polynucleotides may hybridize to the nucleotide sequence of SEQ ID NO: 6.

Additionally, according to MPEP § 2164.06, "the guidance and ease in carrying out an assay to achieve the claimed objectives may be an issue to be considered in determining the quantity of experimentation needed. For example, if a very difficult and time consuming assay is needed to identify a compound within the scope of the claim, then this great quantity of experimentation should be considered in the overall analysis". The specification's general discussion of making and screening for variants constitutes an invitation to experiment by trial and error. Such trial and error experimentation is considered undue. Certain positions in the polypeptide sequence are critical to the protein's structure/function relationship, e.g., such as various sites or regions directly involved in binding, activity, and in providing the correct three-dimensional spatial orientation of binding and active sites. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone (Bork, 2000, Genome Research 10:398-400; Skolnick et al., 2000, Trends in Biotech. 18(1):34-39, especially p. 36 at Box 2; Doerks et al.,

1998, Trends in Genetics 14:248-250; Smith et al., 1997, Nature Biotechnology 15:1222-1223; Brenner, 1999, Trends in Genetics 15:132-133; Bork et al., 1996, Trends in Genetics 12:425-427). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the hOT7T175 protein and DNA which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. A large quantity of experimentation would be required by the skilled artisan to generate the infinite number of derivatives recited in the claims and screen the same for activity. As was found in Ex parte Hitzeman, 9 USPQ2d 1821 (BPAI 1987), a single embodiment may provide broad enablement in cases involving predictable factors such as mechanical or electrical elements, but more will be required in cases that involve unpredictable factors such as most chemical reactions and physiological activity. See also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970); Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991).

(ii) Applicant asserts that claims 8-9 have been limited to diseases associated with dysfunction of the receptor to cancer due to *in vivo* cancer metastasis suppressing activity as described at pg 90, line 33 to pg 91, line 7. Applicant also argues that these claims have been amended to the subject matter indicated as enabled by the Examiner.

Applicant's arguments have been fully considered but are not found to be persuasive. It is noted that the Examiner has interpreted the phrases "which is for the diagnosis of cancer" and "which is for the treatment of cancer" as intended uses of the polynucleotide. For clarification,

the Examiner *did not* indicate in the previous Office Action that the claims were enabled for diagnosis or treatment of cancer. The Examiner simply stated that undue experimentation would be required of the skilled artisan to determine a nexus between hOT7T175 expression and all possible diseases that were encompassed in the claims, except cancer. The specification of the instant application asserts that the receptor protein is useful for prophylactic or therapeutic drug of all cancers (pg 70, lines 18-26). The Examiner discussed other factors which do not enable one skilled in the art to make and/or use the claimed invention. Specifically, the specification of the instant application does not disclose any methods or working examples that indicate the polynucleotide of SEQ ID NO: 6 is a diagnostic or therapeutic for any diseases, including cancer. Undue experimentation would be required of the skilled artisan to determine such. For example, is the hOT7175 gene overexpressed or underexpressed in a cancer tissue sample as compared to normal control? What expression levels must be observed in order for the skilled artisan to diagnose cancer (i.e., how high or low compared to control)? Is gene expression limited to particular tissues or types of cancers? The state of the art is also such that several factors may distort diagnostic tests, such as the distribution of different disease states among the patients, the prevalence of comorbid conditions, the range of pathologic subtypes, how disease status was classified, among others (see Tannock and Hill, The Basic Science of Oncology, 1998, McGraw-Hill: New York; pg 466-474, especially pg 470, col 1 and Table 20.1). Without more specifics about necessary sample size, cancer types, and expression level range for normal and tumor tissues, the specification has not provided the invention in a form readily usable by the skilled artisan such that significant further experimentation is unnecessary.

Additionally, as discussed in the previous Office Action, the specification does not teach

any methods or working examples that indicate a hOT7T175 nucleic acid is introduced and expressed in the cell of an organism for therapeutic purposes, particularly treatment of cancer. The disclosure in the specification is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. The Examiner cited Phillips in the previous Office Action as evidence that gene therapy has generally been inadequate for a meaningful clinical response. Therefore, undue experimentation would be required of the skilled artisan to introduce and express a hOT7T175 nucleic acid into the cell of an organism to treat cancer.

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, to diagnose cancer and to introduce and express a hOT7T175 nucleic acid into a cell of an organism; the lack of direction/guidance presented in the specification regarding the same; the absence of working examples directed to same; the complex nature of the invention; and the state of the prior art which establishes the which establishes the unpredictability of the effects of mutation on protein structure and function and the unpredictability of transferring genes into an organism's cells, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

11. Claims 2-3, 7-9, and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. The basis for this rejection is set forth at pg 8-11 of the previous Office Action of 12 April 2006.

Claim 2 recites an isolated polynucleotide comprising a nucleotide sequence which hybridizes under high stringent conditions to the nucleotide sequence of SEQ ID NO: 6, wherein the high stringent conditions comprise a sodium concentration at about 19mM and a temperature at about 65° C. Claim 7 recites an agent comprising the polynucleotide. Claim 17 is directed to a recombinant vector comprising the polynucleotide and claim 18 is directed to an isolated transformant. It is noted that the Examiner has interpreted claim 2 as encompassing an infinite number of polynucleotides that hybridize to the nucleic acid sequence of SEQ ID NO: 6.

Applicant's arguments (12 July 2006), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant asserts that Applicant asserts that amended claim 1 now requires a nucleotide sequence, which hybridizes under high stringent conditions to the nucleotide sequence of SEQ ID NO: 6, wherein the high stringent conditions comprise a sodium concentration at about 19mM and a temperature at about 65° C.

Applicant's argument has been fully considered but is not found to be persuasive. The claims do not require that the nucleic acid or polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acids that is defined only by hybridization to SEQ ID NO: 6. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or

chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, there is no identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Additionally, the description of one polynucleotide species (SEQ ID NO: 6) and one polypeptide species (SEQ ID NO: 5) is not adequate written description of an entire genus of functionally equivalent polynucleotides which incorporate all variants and fragments that hybridize to a nucleic acid comprising the sequence of SEQ ID NO: 6.

Furthermore, claim 2 and the instant specification only recite a sodium concentration of 19mM and a temperature 65° C as the high stringent conditions. The state of the art is such that the washing conditions in a hybridization assay remove unbound or non-specifically bound sequences, washing away unwanted signal and background (Herzer and Englert. "Nucleic Acid Hybridization". (2001) Molecular Biology Problem Solver: A Laboratory Guide. New York:Wiley-Liss, page 434-345; Wallace et al., Methods Enzym 152: 432-442, 1987, especially pg 439-440; pg 6.58 of "Molecular Cloning: A Laboratory Manual", as cited by Applicant). Thus, regarding claims 2-3, 7-9, and 17-18, since there is no recitation of washing conditions in the claims, an infinite number of polynucleotides may hybridize to the nucleotide sequence of SEQ ID NO: 6.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
Art Unit 1647
27 September 2006

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER